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HORNING, MICHELLE S	
ART UNIT	**PAPER NUMBER**
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,789	STENLAND ET AL.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18, 23-30 and 32-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18, 23-30 and 32-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to communication filed 11/8/2006. The status of the claims is as follows: claims 1-18, 23-30 and 32-36 are under current examination.

The following objections or rejections have been dropped as a result of persuasive arguments by the Applicants:

1. Claim Objections;

2. 35 USC 112, 2nd;

3. 35 USC 102 (e) (Montalto); and

4. 35 USC 103 (a) (Montalto and Prusiner).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 12, 15-18, 29-30 and 32-36 are rejected under 35 U.S.C. 102(e) as being anticipated by US Application 2005/0014196 (hereinafter as "Carbonell et al"). The limitations of the rejected claims above are as follows:

1. A method of preparing a solution containing biological material, comprising

a) adding a metal oxide to biological material to obtain a solution comprising a mixture of the metal oxide and the biological material; and

b) separating the metal oxide from the mixture to form a resulting solution, wherein pathogenic prion proteins possibly contaminating the biological material are substantially reduced in the resulting solution.

2. A method of preparing a solution containing biological material, comprising

a) adding a metal oxide to biological material to obtain a solution comprising a mixture of the metal oxide and the biological material;

b) separating the metal oxide from the mixture to form a resulting solution; and

c) evaluating the resulting solution for the presence or amount of pathogenic prion protein, wherein pathogenic prion proteins possibly contaminating the biological material are substantially reduced in the resulting solution.

3. The method of claim 2, wherein the biological material is selected from the group consisting of blood-derived products, tissue-derived products, and recombinantly produced products.

4. The method of claim 2, wherein the biological material is a blood-derived product.

5. The method of claim 4, wherein the blood-derived product is of human origin.

6. The method of claim 4, wherein the blood-derived product is selected from the group consisting of immunoglobulins, blood coagulation factors, plasmin, plasminogen, ct-1 proteinase inhibitor, and albumin.

7. The method of claim 2, wherein the metal oxide is selected from the group consisting of fumed silica and fumed alumina.

8. The method of claim 2, wherein the fumed metal oxide is fumed silica.

12. The method of claim 2, wherein separating the metal oxide from the mixture comprises filtration.

15. The method of claim 2, wherein evaluating the resulting solution for the presence or amount of pathogenic prion protein comprises evaluating a sample for infectivity using an assay selected from the group consisting of an animal bioassay or an immunoassay for the pathogenic prion protein.

16. The method of claim 2, wherein evaluating the resulting solution for the presence or amount of pathogenic prion protein comprises evaluating a sample for the presence of pathogenic prion protein using an immunoassay.

17. The method of claim 16, wherein the immunoassay is selected from the group consisting of Western blots and ELISA assays.

18. The method of claim 16, wherein the immunoassay is a Western blot.

29. A method of preparing a solution containing biological material, comprising

a) adding silicon dioxide particles to biological material to obtain a solution comprising a mixture of silicon dioxide particles and the biological material; b) separating the silicon dioxide particles from the mixture to form a resulting solution; and

c) evaluating the resulting solution for the presence or amount of pathogenic prion protein, wherein pathogenic prion proteins possibly contaminating the biological material are substantially reduced in the resulting solution.

30. The method of claim 29, wherein separating the silicon dioxide particles from the mixture comprises centrifugation or filtration.

32. A method of separating prions from a sample, comprising

a) contacting a sample in a flowable liquid state with a solid substrate comprising a metal oxide;

b) allowing the sample to remain in contact with the substrate for a time such that prions in the sample bind to the substrate; and

c) separating the sample from the substrate.

33. The method of claim 32, wherein the metal oxide is silicon dioxide or aluminum hydroxide.

34. The method of claim 32, wherein the metal oxide is fumed silica.

35. A method of separating prion proteins from a sample and concentrating them for further analysis, the method comprising, a) contacting the sample with a particulate metal oxide; b) separating the particulate metal oxide from the sample; c) subjecting prion proteins associated with the particulate metal oxide to further analysis.

36. The method of claim 35, wherein the further analysis of prion proteins comprises at least one analytical technique selected from the group consisting of immunoassay, animal bioassay, spectroscopic analysis, and chromatographic analysis.

Carbonell et al discloses an invention that relates to prion protein binding, materials which binds these proteins and methods of using these materials in order to detect or remove prions from biological samples (see Title and Introduction). Such removal of prion protein is "essential when the biological fluid is transmitted to another animal or human, such as in a blood transfusion or the administration of a blood product

such as a clotting factor" (paragraph 12). More specifically, this reference discloses using inorganic materials as prion binding materials, including aluminum oxide and fumed silica (see paragraph 41). Paragraph 24 defines the term "blood-derived compositions" to include whole blood, red blood cell concentrate, plasma, serum, platelet rich and platelet poor fractions, platelet concentrates, white blood cells, blood plasma precipitates, blood plasma fractionation precipitates and supernatants, immunoglobulin preparations including IgA, IgE, IgG and IgM, purified coagulation factor concentrates, fibrinogen concentrate, plasma fractionation intermediate, albumin preparation, or various other substances which are derived from human or animal blood.

Carbonell et al make the following recitation in paragraph 63: "The binding material is allowed to contact a sample, such as a biological fluid, under conditions sufficient to cause formation of a prion -binding material complex, and prion protein in the sample binds to the binding material. The binding material is then separated from the sample, thereby removing the prion protein bound to the ligand from the sample." Example 4 reveals the Western Blot procedures used for the assessment of recovered or depleted infectious and non-infectious prion proteins from solutions of brain homogenates spiked into red blood cell concentrates. The immunodetection of prion proteins was carried out by using specific primary mouse monoclonal antibodies specific to prion proteins (see paragraphs 137-149).

Further, regarding separating the binding material from the mixture, Carbonell et al discloses the following recitation in paragraph 39: "The binding materials provided herein bind to peptides or polypeptides derived from the prion protein, or the entire prion molecule and can be used in a variety of separation processes, including but not limited to, chromatography, such as, but not limited to, thin-layer, column and batch chromatography; solid support and membrane separation; reactor separation; magnetic separation; immunoseparation; and colloidal separation. In one preferred embodiment, the binding materials are contained in a column such as a chromatography column, and a sample is introduced into and allowed to pass through the column so that prion proteins in the sample bind to the binding materials and are retained on the column. The other components of the sample pass through the column and may be collected. It is to be understood that use of the binding materials described herein is not limited to batch or column chromatography. A variety of configurations, modifications and variations of the use of the binding materials for binding prion proteins are envisioned and fall within the scope of the present invention. Such variations and modifications include, but are not limited to: batch processes; continuous processes; moving bed chromatography processes; low, medium, or high pressure processes; or small, medium or large

scale processes. In alternative embodiments, the binding materials are on a membrane, fiber, bead, impregnated into a non-woven mesh, coating a fiber, contained within a filter housing, and the like." With the above recitation, the limitation of filtration is met as well as using a solid substrate as the binding material. Thus, Carbonell et al meet all of the limitations of the claim rejected above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 8-11, 13-14 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carbonell et al. The limitations of the claims above are as follows:

2. A method of preparing a solution containing biological material, comprising

a) adding a metal oxide to biological material to obtain a solution comprising a mixture of the metal oxide and the biological material;

b) separating the metal oxide from the mixture to form a resulting solution; and

c) evaluating the resulting solution for the presence or amount of pathogenic prion protein, wherein pathogenic prion proteins possibly contaminating the biological material are substantially reduced in the resulting solution.

8. The method of claim 2, wherein the fumed metal oxide is fumed silica.

9. The method of claim 8, wherein the fumed silica is characterized by a specific surface area of from about 130 m2/g to about 380 m2/g.

10. The method of claim 8, wherein the fumed silica is characterized by a specific surface area of from about 150 ma/g to about 300 mZ/g.

11. The method of claim 8, wherein the fumed silica is characterized by a specific surface area of about 200 m2/g.

13. The method of claim 12, wherein the filtration comprises passing the mixture through a filtration system which retains particles larger than from about 0.1 um to about 5 um.

14. The method of claim 12, wherein the filtration comprises passing the mixture through a filtration system which retains particles larger than about 0.8 um.

23. A method of preparing a solution containing biological material, comprising

a) adding fumed silica characterized by a specific surface area of from about 150 mE/g to about 300 m2/g to biological material to obtain a solution comprising a mixture of fumed silica and the biological material;

b) separating the fumed silica from the mixture to form a resulting solution by passing the mixture through a filtration system comprising a filter which retains at least a substantial portion of particles of the fumed silica; and

c) evaluating the resulting solution for the presence or amount of pathogenic priori protein using an immunoassay, wherein pathogenic prion proteins possibly contaminating the biological material are substantially reduced in the resulting solution.

24. The method of claim 23, wherein the fumed silica is characterized by a specific surface area of about 200 m2/g, a tap density of about 50 g/l, and an average aggregate particle length of from about 0.2 um to about 0.3 um.

25. The method of claim 23, wherein the fumed silica is added in an amount from about 0.1% to about 1.0% (weight/weight) of the solution comprising a mixture of fumed silica and the biological material.

26. The method of claim 23, wherein the fumed silica is added in an amount from about 0.2% to about 0.8% (weight/weight) of the solution comprising a mixture of fumed silica and the biological material.

27. The method of claim 23, wherein the fumed silica is added in an amount of at least about 0.25% (weight/weight) of the solution comprising a mixture of fumed silica and the biological material.

28. The method of claim 23, wherein the fumed silica is added in an amount of at least about 0.5% (weight/weight) of the solution comprising a mixture of fumed silica and the biological material.

As discussed above, the limitations of claims 2 and 8 have been met by the teachings of Carbonell et al. While this reference does not discuss surface areas of fumed silica, amounts of fumed silica to use or retention of particles based on specific size exclusions, Carbonell et al makes the following recitation (paragraph 45): "The binding materials are preferably in particulate, granular or bead form. Particulate binding materials preferably have a particle, or bead, size ranging from approximately 1 um to 500 um, and more preferably from approximately 20 um to 150 um." It would have been obvious to the ordinary artisan to adjust the variables mentioned above, including surface areas of binding materials and amount of fumed silica used, according to the conditions of the biological starting materials. Further, it would have obvious to the ordinary artisan to use a membrane filter with pores smaller than the binding material or binding material complexed to prions in order to retain them during the separation process. One would have been motivated to adjust these variables to gain optimized results. There would have been a reasonable expectation of success given such adjustments are well known and widely used in the prior art. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

NO claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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